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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Saito et al.

Art Unit: 1644

Application No. 09/706,301

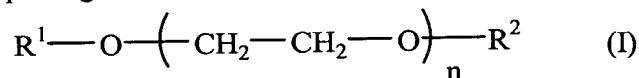
Examiner: G. R. Ewoldt

Filed: November 3, 2000

For: OIL ADJUVANT VACCINE

**PENDING CLAIMS AFTER AMENDMENTS
MADE IN RESPONSE TO OFFICE ACTION DATED NOVEMBER 1, 2002**

1. A W/O/W type oil adjuvant vaccine comprising (a) an inner aqueous phase comprising a biologically acceptable and effective amount of antigen, (b) an oil component phase which is in a liquid state at a temperature in the range of 15-25 °C, and (c) an outer aqueous phase comprising 0.5 - 20 wt% of a polyethylene glycol derivative having a



molecular weight of 400 - 20,000, which is represented by the following formula (I)

wherein R^1 and R^2 may be the same or different and each is a hydrogen atom or alkyl having 1 to 4 carbon atoms and n is a polymerization degree, and wherein the inner aqueous phase is discontinuous and suspended in the oil component phase, and the oil component phase is discontinuous and suspended in the outer aqueous phase.

2. The oil adjuvant vaccine of claim 1, wherein the polyethylene glycol derivative of the formula (I) has a molecular weight of 1,000 - 10,000.

3. The oil adjuvant vaccine of claim 1, wherein the outer aqueous phase comprises 1 - 10 wt% of the polyethylene glycol derivative of the formula (I).

4. The oil adjuvant vaccine of claim 1, which is a W/O/W type oil adjuvant vaccine prepared by the steps of

(a) preparing a W/O emulsion comprising an oil component (A) which becomes liquid at room temperature, an emulsifier (B) and an aqueous component (C) comprising a biologically acceptable and effective amount of an antigen, and

(b) dispersing or emulsifying the W/O emulsion in a liquid comprising an emulsifier (D) and an aqueous component (E), wherein the liquid comprises 0.5 - 20 wt% of a polyethylene glycol derivative having a molecular weight of 400 - 20,000, which is represented by the formula (I).

5. The oil adjuvant vaccine of claim 1, which is a W/O/W type oil adjuvant vaccine prepared by the steps of

(a) preparing a W/O emulsion comprising an oil component (A) which becomes liquid at room temperature, an emulsifier (B) and an aqueous component (C) comprising a biologically acceptable and effective amount of an antigen,

(b) dispersing or emulsifying the W/O emulsion in a liquid comprising an emulsifier (D) and an aqueous component (E), and

(c) adding a polyethylene glycol derivative having a molecular weight of 400 - 20,000, which is represented by the formula (I), to the outer aqueous phase to a concentration of 0.5 - 20 wt%.

6. The oil adjuvant vaccine of claim 4, wherein the oil component (A), which becomes liquid at room temperature, comprises a fatty acid ester or squalene or a fatty acid ester and squalene in a proportion of not less than 20 wt% of an oil phase.

7. The oil adjuvant vaccine of claim 4, wherein the emulsifier (B) has an HLB of less than 10.

8. The oil adjuvant vaccine of claim 7, wherein the emulsifier (B) comprises at least one member selected from the group consisting of a partial ester of polyhydric alcohol and a fatty acid, and a non-ionic surfactant having a polyoxyethylene chain.

9. The oil adjuvant vaccine of claim 4, wherein the emulsifier (D) has an HLB of not less than 10.

10. The oil adjuvant vaccine of claim 9, wherein the emulsifier (D) comprises a non-ionic surfactant having a polyoxyethylene chain.

11. The oil adjuvant vaccine of claim 5, wherein the oil component (A), which becomes liquid at room temperature, comprises a fatty acid ester or squalene or a fatty acid ester and squalene in a proportion of not less than 20 wt% of an oil phase.

12. The oil adjuvant vaccine of claim 5, wherein the emulsifier (B) has an HLB of less than 10.

13. The oil adjuvant vaccine of claim 12, wherein the emulsifier (B) comprises at least one member selected from the group consisting of a partial ester of polyhydric alcohol and a fatty acid, and a non-ionic surfactant having a polyoxyethylene chain.

14. The oil adjuvant vaccine of claim 5, wherein the emulsifier (D) has an HLB of not less than 10.

15. The oil adjuvant vaccine of claim 14, wherein the emulsifier (D) comprises a non-ionic surfactant having a polyoxyethylene chain.

16. The oil adjuvant vaccine of claim 1, wherein the outer aqueous phase comprises 1 - 5 wt% of the polyethylene glycol derivative of the formula (I).

17. The oil adjuvant vaccine of claim 1, wherein the polyethylene glycol derivative of the formula (I) has a molecular weight of 3,000 - 9,000.